

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
v. )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8404

Bartle, C.J.

March 1, 2010

Richard Hernon ("Mr. Hernon" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement §§ IV.B.1.a. & I.22.

In February 2002, claimant submitted a Green Form to the Trust signed by his attesting physician, Andrew M. Keller, M.D., F.A.C.C., F.A.C.P. Based on an echocardiogram dated April 14, 2000, Dr. Keller attested in Part II of Mr. Hernon's

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2. (...continued)  
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

Green Form that he suffered from mild aortic regurgitation and aortic stenosis<sup>3</sup> and that he underwent surgery to replace his aortic valve.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix B-1, Level III benefits in the amount of \$127,286.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, John H. Arthur, M.D., made no comment regarding the presence of aortic regurgitation. Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is equal to or greater than 10% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

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3. Under the Settlement Agreement, the presence of aortic stenosis requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)e).

4. Dr. Keller also attested that claimant suffered from mild mitral regurgitation, an abnormal left atrial dimension, an ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits if he or she had "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Mr. Hernon underwent surgery to repair or replace the aortic valve following the use of Pondimin® and/or Redux™, the only issue is whether claimant is eligible for benefits.

In October 2002, the Trust advised Mr. Hernon that his claim had been selected for audit.<sup>6</sup> In response, claimant submitted a copy of an e-mail from Dr. Keller detailing the basis for Dr. Keller's Green Form representation that claimant suffered from mild aortic regurgitation. Specifically, Dr. Keller stated:

I reviewed my paper work on this submission. Frame referenced as "0:06:48:07" from the 4/14/00 study demonstrates aortic regurgitation with a 17% jet height to LVOT height. This would qualify him as mild regurgitation according to criteria. Additionally I also noted that the intraoperative TEE from 4/17/00 demonstrated mild [aortic regurgitation], and that was only two days later ....

In December 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's finding of mild aortic regurgitation. In support of this conclusion, Dr. Irani explained that "[t]race aortic regurgitation seen only in [parasternal long-axis] view."

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6. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. and VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit only claimant's level of aortic regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

Based on the auditing cardiologist's diagnosis of trace aortic regurgitation, the Trust issued a post-audit determination denying Mr. Hernon's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § IV.<sup>7</sup> The Trust then applied to the court for issuance of an Order to show cause why Mr. Hernon's claim should be paid. On August 19, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2979 (Aug. 19, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 22, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor<sup>8</sup> to review

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7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Mr. Hernon's claim.

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (continued...)

claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he had mild aortic regurgitation. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of his claim, Mr. Hernon argues that there is a reasonable medical basis for his attesting physician's finding of mild aortic regurgitation based on the April 14, 2000 and the April 17, 2000 echocardiograms. Specifically, Dr. Keller

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8. (...continued)

(1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

noted that the frame referenced at 0:06:48:07 from the April 14, 2000 echocardiographic study demonstrates aortic regurgitation with a JH/LVOTH ratio of 17%. Claimant submitted a digitally-signed color photocopy of that frame. Finally, claimant contends that the auditing cardiologist's finding of trace aortic regurgitation is insufficient to defeat his claim because Dr. Irani did not refute Dr. Keller's findings or make any notes in the comments section.

After receipt of claimant's Response, the Trust submitted the claim to Dr. Irani for a second review. Dr. Irani confirmed his prior finding that there was no reasonable medical basis for the attesting physician's finding of mild aortic regurgitation. Based on this second review, Dr. Irani signed a declaration, in which he states, in relevant part, that:

In connection with my review, I determined that the aortic jet upon which Claimant's Attesting Cardiologist relies (in the frame appearing at 6:48:07 seconds on Claimant's 4/14/00 echocardiogram tape) is very slender and does not proceed very far into the left ventricular outlet tract. This frame is not representative and, because of its angle, inflates the apparent height of the jet. Indeed, because the view of the proximal part of the jet is oblique, the jet appears taller than it actually is. More representative frames, appearing at 6:36:28 and 6:41:01 seconds on Claimant's echocardiogram tape, demonstrate that Claimant's level of aortic regurgitation is only trace.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding

that claimant had mild aortic regurgitation. In particular, Dr. Vigilante stated that:

I reviewed the chest wall echocardiogram performed on April 14, 2000. This clearly demonstrates significant aortic stenosis with trace aortic insufficiency. The aortic regurgitation jet height to left ventricular outflow tract height is less than 10% .... The apical view of the aortic valve demonstrated that aortic insufficiency could not be seen. At frame 6:48:07 seconds, trace aortic insufficiency was seen.

Review of the transesophageal intraoperative echocardiogram of April 17, 2000 also shows trace aortic insufficiency with severe aortic stenosis .... The best view for evaluating the aortic insufficiency on this study was the left ventricular outflow tract view seen when the probe was 121 degrees and the tape study at 7:40:34:17.

In response to the Technical Advisor Report, claimant argues that mild aortic regurgitation need not be present throughout the echocardiographic study to conclude that there is a reasonable medical basis for the attesting physician's finding of mild aortic regurgitation. Claimant also contends that Dr. Vigilante improperly found trace aortic insufficiency in the April 17, 2000 echocardiogram. Claimant suggests that Dr. Vigilante based his opinion on the handwritten note on the report of the April 17, 2000 echocardiogram that claimant had trace aortic regurgitation, which, according to Mr. Hernon, represents a post-operative measurement. Finally, claimant argues that Dr. Vigilante failed to address the attesting physician's finding that the April 17, 2000 echocardiogram shows mild aortic regurgitation.

After reviewing the entire Show Cause Record before us, we find that claimant is not eligible to receive Level III Matrix Benefits. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits for "[s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c. (3) (a). Under this definition, claimant, if he were found to be eligible, would have met the requirements of a Level III claim as the Trust does not contest that he had surgery to replace his aortic valve following the use of Pondimin® and/or Redux™.

Claimant, however, must establish his eligibility for benefits. In PTO No. 3192, we noted that simply meeting the definition of Matrix Level III as set forth in the Settlement Agreement is insufficient to qualify for Matrix Benefits. Rather, a claimant also must satisfy the eligibility requirements set forth in Section IV.B.1.a. of the Settlement Agreement. See PTO No. 3192 at 3 ("Experiencing left sided valvular heart disease is of no moment unless the claimant also passes muster under § IV.B.1.a.").

The Settlement Agreement states that the following Class Members are eligible to receive Matrix Compensation Benefits:

Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of

the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement defines FDA Positive, in pertinent part, as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, claimant must prove at least mild aortic regurgitation to be eligible to seek Matrix Benefits for his Level III aortic valve claim.

Claimant, however, has not established that there is a reasonable medical basis for his attesting physician's finding that Mr. Hernon suffers from mild aortic regurgitation. First, we disagree with claimant that he may prove mild aortic regurgitation by relying on a single frame from an echocardiogram. For a reasonable medical basis to exist, a claimant must demonstrate that a finding of the requisite level of regurgitation is representative of the level of regurgitation throughout an echocardiogram.<sup>9</sup> To conclude otherwise would allow claimants who do not have mild aortic regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

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9. Under the Settlement Agreement, mild or greater aortic regurgitation is defined as a JH/LVOTH ratio equal to or greater than 10%. See Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on an isolated instance of what appears to be the requisite level of regurgitation to meet this definition.

As we previously have stated, "'[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment ....'" PTO No. 6897 at 7 (Jan. 26, 2007) (quoting PTO No. 2640 at 9) (finding that assessment of threshold level of mitral regurgitation may not be made on basis of single regurgitant jet). The same requirement applies to the assessment of aortic regurgitation. Claimant has failed to establish a reasonable medical basis for his claim because he has not demonstrated that the "subject frame" offered in support of his claim is representative of his level of aortic regurgitation. We reject claimant's argument that the level of aortic regurgitation to which Dr. Keller attested need not be representative of the study as a whole.

Here, the auditing cardiologist, Dr. Irani, and the Technical Advisor, Dr. Vigilante, have reviewed the echocardiograms submitted by claimant and determined that they do not support the attesting physician's Green Form representation. Specifically, the auditing cardiologist reviewed claimant's April 14, 2000 echocardiogram and determined that it demonstrates trace aortic regurgitation. With respect to the frame at 0:06:48:07, Dr. Irani found that the aortic jet in that frame was "slender and does not proceed very far into the left ventricular outlet tract. This frame is not representative and, because of its angle, inflates the apparent height of the jet. Indeed, because the view of the proximal part of the jet is oblique, the

jet appears taller than it actually is." We reject claimant's argument that Dr. Irani did not support his findings.

In addition, Dr. Vigilante reviewed both the April 14, 2000 and the April 17, 2000 echocardiograms. With respect to the April 14, 2000 echocardiogram, Dr. Vigilante found that it "clearly demonstrates ... trace aortic insufficiency."

Dr. Vigilante added: "[a]t frame 6:48:07 seconds, trace aortic insufficiency was seen." With respect to the April 17, 2000 echocardiogram, Dr. Vigilante found that a "[r]eview of the transesophageal intraoperative echocardiogram of April 17, 2000 also shows trace aortic insufficiency."<sup>10</sup> Rather than rebut these specific findings, claimant relies solely on Dr. Keller's representations and erroneous interpretations of the Settlement Agreement. On this basis as well, claimant has failed to meet his burden of establishing a reasonable medical basis for the attesting physician's finding that Mr. Hernon suffered from mild aortic regurgitation.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for his claim. Therefore, we affirm the Trust's denial of his claim for Matrix Benefits.

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10. We find without merit claimant's arguments that the Technical Advisor: (1) relied on the April 17, 2000 "Intraoperative Echocardiography Report" rather than an independent review of the April 17, 2000 echocardiogram and (2) failed to discuss or address Dr. Keller's finding that the April 17, 2000 echocardiogram demonstrates mild aortic regurgitation.